

K123092

510(k) Summary

per 21CFR807.92

CONTACT:

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TOMY, Inc.
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Japan

DEC 21 2012

DATE PREPARED: November 2, 2012

TRADE OR PROPRIETARY NAME: CERAMIC BRACKETS Z

CLASSIFICATION NAME: Bracket, Ceramic, Orthodontic, 872.5470

PREDICATE DEVICES:

Clarity Advance Ceramic Brackets (K102803)
In-Ovation C ceramic brackets (K060837)

DEVICE DESCRIPTION: The CERAMIC BRACKETS Z are designed to move teeth to improve their alignment.

The CERAMIC BRACKETS Z are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.

No accessories are marketed with the CERAMIC BRACKETS Z. The dental clinician is free to choose the bonding cement, supplemental ligatures and orthodontic wires for use with the brackets.

INTENDED USES: The CERAMIC BRACKETS Z are indicated for orthodontic movement on natural teeth surfaces.

TECHNOLOGICAL CHARACTERISTICS: The CERAMIC BRACKETS Z are composed of a polycrystalline zirconia ceramic bracket, which includes an archwire slot and tiewings. The self-ligating CERAMIC BRACKETS Z have a metal clip so that no other ligation of the archwire is needed.

Bench testing was performed to ensure that the CERAMIC BRACKETS Z performance was achieved and validated, including shear bond tests and torque (fracture) tests.

The CERAMIC BRACKETS Z were not evaluated for biocompatibility because zirconia has a history of safe use in medical devices. All of the components have been used in legally marketed predicate CERAMIC BRACKETS Z.

The CERAMIC BRACKETS Z device is substantially equivalent in safety and effectiveness to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

TOMY, Inc.
C/O Carolyn M. Primus, PhD
Consultant
Primus Consulting
7046 Owl's Nest Terrace
Bradenton, FL 34203

Re: K123092

Trade/Device Name: Ceramic Brackets Z
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: September 28, 2012
Received: October 25, 2012

Dear Dr. Primus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123691

Device Name: CERAMIC BRACKETS Z

Indications For Use: CERAMIC BRACKETS Z are indicated for orthodontic movement on natural teeth surfaces.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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Susan Runner DDS, MA
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Tomy, Inc.

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

CERAMIC BRACKETS Z

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